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Art: 714199-00D

Rev. Date: 06/29/04

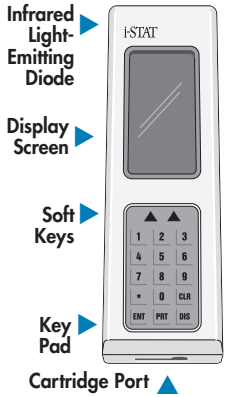
i-STAT

Portable Clinical Analyzer & Test Cartridges

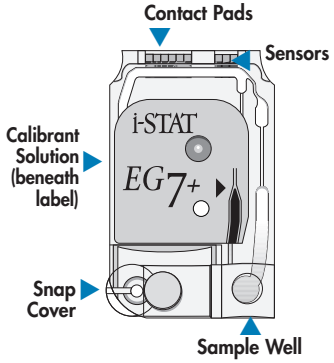
User Guide

System Components

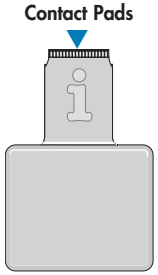
Analyzer



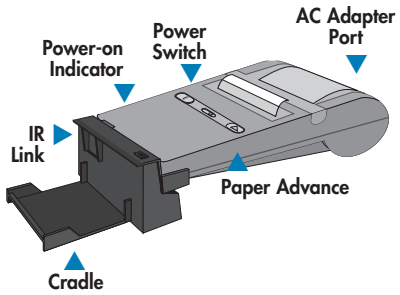
Cartridge



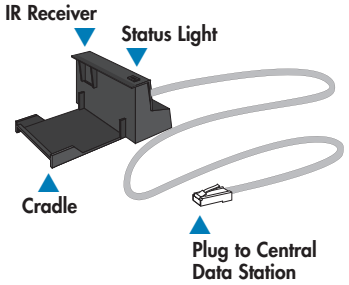
Electronic Simulator



IR Link/Printer Cradle Connected to Printer



IR Link



IVD For *in vitro* diagnostic use.

See System Manual for instructions.

Intended Use: The i-STAT® Portable Clinical Analyzer is intended for use with i-STAT cartridges for the *in vitro* quantification of various analytes in whole blood.

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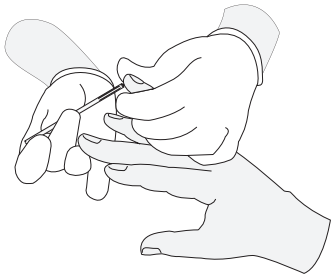
Quality Check Messages and Codes

MESSAGE	ACTION	EXPLANATION
SIM	Use Electronic Simulator	Simulator must be used once every 24 hours, or as needed for regulatory compliance.
BAT	Replace batteries soon	Approximately 50 more cartridges can be tested.
SFT	Update software	Software will expire 15 days after SFT is first displayed.
Date Invalid	Check clock on Status Page.	The software checks for an unrealistic date. Check Status Page. If date is correct, call Technical Services.
Dead Batteries	Replace Batteries	The analyzer does not have enough power to complete the testing cycle.
TEMPERATURE OUT OF RANGE	Check Status Page. Use another cartridge.	The analyzer is too warm or too cool, or the room is too warm or too cool.
CARTRIDGE ERROR	Use another cartridge	The analyzer detected a problem with the calibrant solution.
CARTRIDGE TYPE NOT RECOGNIZED	Use another cartridge	The analyzer could not identify the type of cartridge inserted. Check software version. Check to see if cartridges are expired.
CARTRIDGE PREBURST	Use another cartridge	Calibrant released too soon. Take care not to press over cartridge label area.
SAMPLE POSITIONED SHORT OF FILL MARK	Use another cartridge	Sample did not reach fill mark. Tilt cartridge to aid sample flow into sample chamber.
SAMPLE POSITIONED BEYOND FILL MARK	Use another cartridge	Cartridge is overfilled. Fill new cartridge to fill mark. Press on snap closure, and not over sample well when closing.
INSUFFICIENT SAMPLE	Use another cartridge	Cartridge is underfilled or bubbles trapped in sample.
UNABLE TO POSITION SAMPLE	Use another cartridge	Inadequate seal; sample overflowed well; sample clotted; snap closure left open.
CARTRIDGE NOT INSERTED PROPERLY	Reinsert cartridge	Push cartridge straight through door until it will go no further.
ANALYZER ERROR	Use Electronic Simulator	If the analyzer passes the simulator check, continue to use. If not, call i-STAT Technical Services.
ANALYZER ERROR	See System Manual	See System Manual
SYSTEM INTERRUPTED	Use another cartridge	Conditions such as batteries removed before analyzer deactivated when cartridge is still in analyzer.
Invalid or Expired CLEW	Update software	Software expired or corrupt. Verify that the analyzer's date is correct.

Blood Collection

Acceptable Samples for Cartridges

- Arterial: Plain syringe, heparinized syringe labeled for analytes to be tested and filled to capacity, or syringe with minimum volume of heparin to prevent clotting (10 U/mL of blood). For ionized calcium, use balanced heparin syringes. Mix heparinized syringes by rolling between palms for at least 5 seconds in 2 directions, then invert the syringe repeatedly for at least 5 seconds. Test for lactate immediately. Test for other analytes within 10 minutes.
  - Avoid drawing air into syringes for blood gas and ionized calcium tests.
  - If not tested immediately, remix and discard 2 drops of blood before filling cartridge.
  - Do not use iced samples.
- Venous: Collection tube with lithium or sodium heparin filled to capacity and mixed by gentle inversion at least 10 times. Test within 10 minutes.



  - Do not leave tourniquet on for more than 2 minutes.
  - Do not draw above an I.V.
- Skin puncture: Lithium heparin capillary tubes for testing all analytes but ionized calcium. For all analytes including ionized calcium, use plain or balanced heparin capillary tubes. Test immediately.
  - Allow alcohol to dry over puncture site before collecting sample.
  - Do not "milk" finger or heel while collecting sample.
- Coagulation Tests:
  - The ACT test can be performed using venous or arterial samples, while the PT/INR test can be performed using capillary or venous samples.
  - Use plain plastic syringes or plastic evacuated tubes with no anticoagulant, activators, or serum separators.
  - Test sample immediately upon draw.
  - Some experts recommend drawing and discarding a sample of at least 1 ml prior to drawing samples for coagulation testing.
  - If a second measurement is needed, draw a fresh sample.

- For In-dwelling line testing for ACT:
  a. Fluid drip through the line must be discontinued.
  b. Withdraw 2 ml of blood into a syringe and discard it.
  c. Withdraw the sample into a fresh plastic syringe with no anticoagulant, and test immediately.
- For extracorporeal line testing for ACT:
  a. Flush the extracorporeal blood access line by withdrawing 5 ml of blood into a syringe and discard the syringe.
  b. Withdraw the sample into a fresh plastic syringe with no anticoagulant, and test immediately.
- For skin puncture testing for PT/INR, see the section on "Patient Test Procedures".

Limitations

Interfering substances in the patient's sample may cause an increase or decrease in a result. Refer to the Cartridge Test and Information Sheets and Technical Bulletins for substances and/or conditions that may interfere with cartridge tests.

Troubleshooting

*** Instead of Results

- Draw a fresh sample and use the same lot of cartridge to repeat the test.
- If stars reappear, check the lot of cartridges using liquid controls.
- If the controls are in-range and do not display stars, the sample may have an interfering substance and should be tested by another method.
- If the controls are out-of-range and/or display stars, use another lot of cartridges and report the problem lot to your technical support representative.
- If stars are displayed with a control sample and a second lot of cartridges, there may be debris on the analyzer connector pins. Contact your Support Representative for instructions on how to condition the pins in your analyzer.

Unexpected Results

When results do not reflect the patient's condition:

- Repeat the test using a fresh sample and cartridge.
- If results are still suspect, check the lot of cartridge using liquid controls. If the controls are in-range, there may be an interfering substance in the sample.
- Check the Cartridge and Test Information sheets and any Technical Bulletins related to the tests for any known interfering substances. Test by another method if any interfering substance applies.
- If an applicable interfering substance is not listed, test by another method to verify the result.
- If the control results are out-of-range, use another lot of cartridges or test by another method. Report the problem to your local technical support representative.

1. Insert Electronic Simulator.
   Do not touch the contact pads.
2. If PASS is displayed, remove simulator and continue using analyzer.
3. If FAIL is displayed, remove simulator and repeat. If FAIL is displayed again, contact your i-STAT Technical Service representative. Do not use the analyzer.

Thermal Probes and Room Temperature Checks:

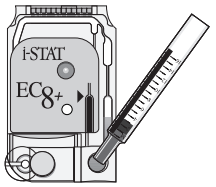
- See System Manual for these quality assurance procedures that are performed once or twice per year.

Cartridge

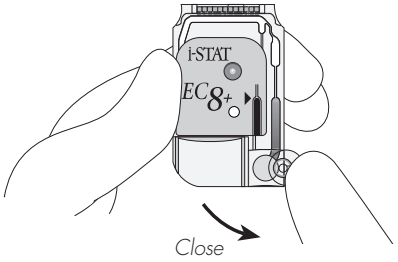
- Check temperature strip enclosed with each shipment of cartridges. If the windows are clear or if the **A** window is blue, or the **1** window is red, the cartridges should be accepted. If **B, C,** or **D** windows are blue, or the **2, 3,** or **4** windows are red, contact Support Services.
- Verify the integrity of a new shipment of cartridges, on receipt, by analyzing 2 levels of i-STAT Controls and Hematronix Meter Trax controls for hematocrit using any verified i-STAT analyzer and a representative sample of the lot(s) of cartridges received. Use the expected values published in the fluids' package inserts to verify the integrity of the cartridges.
- A procedure should be in place to control and monitor proper storage conditions (See Cartridge Handling). Cartridges maintained according to i-STAT storage requirements will retain their performance at least until the expiration date.

Patient Test Procedures

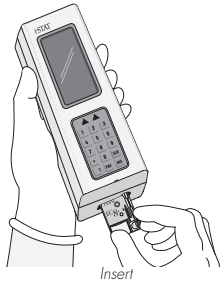
Cartridge Test Procedure



1. Remove cartridge from pouch. Handle a cartridge by its edges. Avoid touching the contact pads or exerting pressure over the center of cartridge.
2. Following thorough mixing of the sample, direct syringe tip, pipette tip or capillary tube into the sample well. Dispense sample until it reaches the fill mark on cartridge.



3. Fold the snap cover over the sample well until it snaps into place. Press on round tab, not over sample well.
4. Insert the cartridge into the cartridge port. For ACT and PT/INR cartridges, keep the analyzer in a horizontal position.



5. Never attempt to remove a cartridge while the LCK message is displayed.
6. Enter operator ID number up to 7 digits. (Repeat operator ID number for verification, if prompted.)
7. Enter patient ID number up to 12 digits. (Repeat patient ID number for verification, if prompted.)
8. Enter blood gas parameters and sample type on chart page if applicable.

Screen display deactivates after 45 seconds to preserve battery life. Results can be redisplayed by pressing the DIS key.

9. View results on the analyzer's display.
10. Remove the cartridge after the LCK message disappears. The analyzer is ready for a new cartridge immediately.

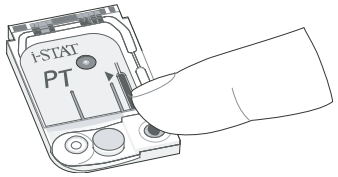
PT/INR (Prothrombin Time) Cartridge Test Procedure

Caution

The i-STAT PT/INR cartridge is designed to accept a sample between 20 and 45 microliters. A single drop of blood from either a finger puncture or as formed at the tip of a syringe will typically be within this range. If a larger volume is delivered to the sample well, use caution when closing the cartridge as excess blood may be expelled from the cartridge.

Skin Punctures

1. Remove cartridge from foil pouch and place the cartridge on a flat surface.
2. Prepare lancet device and set aside until needed.
3. Clean and prepare the finger to be sampled. Allow finger to dry thoroughly before sampling.
4. Prick the bottom side of the fingertip with the lancet device.
5. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. *Avoid strong repetitive pressure ("milking") as it may cause hemolysis or tissue fluid contamination of the specimen.*

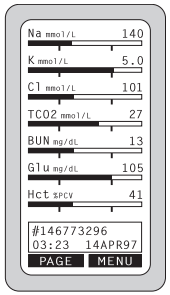


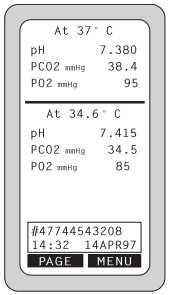
6. Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
7. Apply sample until it reaches the fill mark indicated on the cartridge.
8. Fold the sample closure over the sample well.
9. Press the rounded end of the closure until it snaps into place.

Note: To further simplify the sample application into the test cartridge, it is possible to bring the cartridge to the finger for easier application. Do ensure that the instrument remains on a level vibration-free surface for testing.

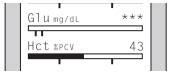
Reviewing Tests Results

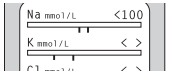
- Test results are displayed numerically, and with bar graphs. Tick marks indicate the reference ranges on the bar graphs. (Blood gases, coagulation tests and their associated calculated values are not displayed with bar graphs and reference ranges.)





- Results that are unreportable due to sensor errors or interfering substances are flagged with "***".



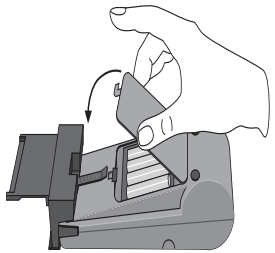


- Results outside the reportable range are flagged with "<" or ">".

Replacing the Batteries in the HP Portable Printer

Install fresh batteries when any of the following conditions occur:

- Print contrast is uncomfortably low, even when the print control is set to highest contrast.
- Printing slows because the print head moves across the paper at a much slower speed. (When a large amount of information—more than 200 characters—is transmitted by the analyzer, printing slows because the printer pauses momentarily before printing each new line. However, the print head moves across the paper at normal speed. This is not a symptom of low batteries.)
- Printing halts before all information on a line has been printed.
- Battery condition index printed at the end of the self test is 1 or 0.

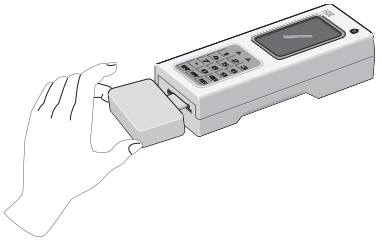


Step	Action
1	Turn the printer upside down and open the battery compartment as shown in the illustration.
2	Remove old batteries.
3	Align fresh 1.5 volt AA alkaline batteries with the + and - symbols in the battery compartment and insert the batteries.
4	Replace the battery compartment door.

Quality Assurance

Analyzer

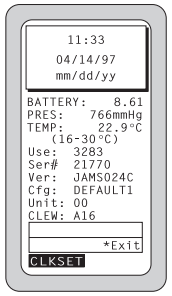
Electronic Simulator:



- Perform an electronic check on each analyzer once a day using the Internal or External Electronic Simulator or as needed for regulatory compliance. The internal simulator check is initiated every 24 hours or according to a customized schedule, when a cartridge is inserted into the cartridge port. If the internal simulator result is **PASS**, the cartridge test proceeds and the simulator results are stored. If **FAIL** is displayed for the internal simulator, reinsert the cartridge or use an external simulator. The external simulator check is performed as follows:

Changing Date & Time

1. Press the Menu softkey and select Status.
2. Press the CLKSET softkey to convert the softkeys into arrows.
3. Using the arrow keys, move the cursor under the digit to be changed.
4. Use the keypad to change the digit.
5. When all changes are made, press the ENT key to store the changes. Note that the clock is 24 hours. The analyzer will not store inappropriate entries.

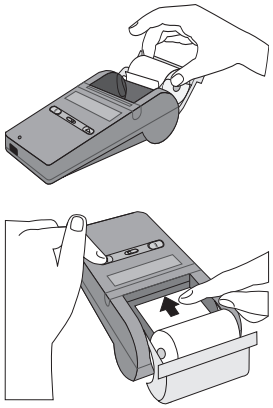


Cleaning the Analyzer

- Clean the display and case with a gauze pad moistened with a mild non-abrasive cleaner, detergent, soap and water, alcohol, or 10% bleach solution. Rinse with another pad moistened with water and dry.

Replacing the Paper in the HP Portable Printer

Loading the Paper



Step	Action
1	Open paper compartment door.
2	Make sure that leading edge of paper is cut evenly.
3	Position paper in door as shown in illustration.
4	Turn the printer on by switching the on/off switch to the on (|) position.
5	While pushing paper into slot, hold down the paper advance switch until paper emerges. If paper jams, pull backwards very slowly.
6	Place paper in compartment and close the door.

Caution

- Do not operate printer without paper.
- Do not pull paper through mechanism, use the paper advance switch.
- Do not pull paper backward through printer.
- Do not run paper to end of roll if paper is attached to its inner core. Paper supplied by i-STAT is not attached.

Reportable and Reference Range

Measured:

Test	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Sodium/Na	mmol/L (mEq/L)	100 – 180	138 – 146	138 – 146
Potassium/K	mmol/L (mEq/L)	2.0 – 9.0	3.5 – 4.9	3.5 – 4.9
Chloride/Cl	mmol/L (mEq/L)	65 – 140	98 – 109	98 – 109
Glucose/Glu	mmol/L mg/dL g/L	1.1 – 38.9 20 – 700 0.20 – 7.00	3.9 – 5.8 70 – 105 0.70 – 1.05	3.9 – 5.8 70 – 105 0.70 – 1.05
Lactate/Lac	mmol/L mg/dL	0.30 – 20.00 2.7 – 180.2	0.36 – 1.25 3.2 – 11.3	0.90 – 1.70 8.1 – 15.3
Creatinine/Crea	mg/dL µmol/L	0.2 – 20.0 18 – 1768	0.6 – 1.3 53 – 115	0.6 – 1.3 53 – 115
pH		6.5 – 8.0	7.35 – 7.45	7.31 – 7.41
PCO_2	mmHg kPa	5 – 130 0.67 – 17.33	35 – 45 4.67 – 6.00	41 – 51 5.47 – 6.80
PO_2	mmHg kPa	5 – 800 0.7 – 106.6	80 – 105 10.7 – 14.0	
Ionized Calcium/iCa	mmol/L mg/dL	0.25 – 2.50 1.0 – 10.0	1.12 – 1.32 4.5 – 5.3	1.12 – 1.32 4.5 – 5.3
Urea Nitrogen/BUN Urea	mg/dL mmol/L mg/dL	3 – 140 1 – 50 6 – 300	8 – 26 2.9 – 9.4 17 – 56	8 – 26 2.9 – 9.4 17 – 56
Hematocrit/Hct	%PCV Fraction	10 – 75 0.10 – 0.75	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51
Celite Activated Clotting Time / Celite ACT	seconds	50 – 1000	74 – 125 (Prewrm) 84 – 139 (Nonwrm)	74 – 125 (Prewrm) 84 – 139 (Nonwrm)
The range from 80 - 1000 seconds has been verified through method comparison studies.				
Kaolin Activated Clotting Time / Kaolin ACT	seconds	50 – 1000	74 – 137 (Prewrm) 82 – 152 (Nonwrm)	74 – 137 (Prewrm) 82 – 152 (Nonwrm)
The range from 77 - 1000 seconds has been verified through method comparison studies.				
Prothrombin Time / PT	INR	0.9 – 8.0		
Performance characteristics have not been established for INRs above 6.0.				

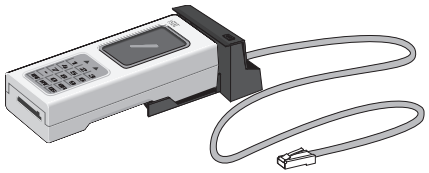
Celite is a registered trademark of Celite Corporation, Santa Barbara, CA., for its diatomaceous earth products.

Calculated:

Test	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Hemoglobin/Hb	g/dL g/L mmol/L	3.4 – 25.5 34 – 255 2.1 – 15.8	12 – 17 120 – 170 7 – 11	12 – 17 120 – 170 7 – 11
TCO_2	mmol/L (mEq/L)	1 – 85	23 – 27	24 – 29
HCO_3	mmol/L (mEq/L)	1.0 – 85.0	22 – 26	23 – 28
BE	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3)	(-2) – (+3)
Anion Gap/AnGap	mmol/L (mEq/L)	(-10) – (+99)	10 – 20	10 – 20
sO_2	%	0 – 100	95 – 98	

Transmitting Test Results

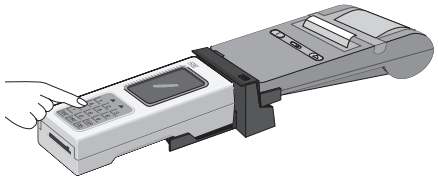
1. Place the analyzer in the IR Link cradle. The IR Link light should be green.
2. With results displayed, press the * key.
3. The IR Link light will blink alternately red and green until transmission is complete.



The IR Link will emit a single high pitched beep when transmission has been successful; an unsuccessful transmission is indicated by 3 low tone beeps. (Try again)

Printing Test Results

1. Place the analyzer in the IR Link or Printer Cradle as shown. Turn the printer on. The power indicator light should be lit.
2. To print the displayed test record, press the PRT key.
3. To print a stored test record(s), select "Print Results" from the Stored Results menu. Select records to be printed by pressing key(s) corresponding to numbers beside record(s). Then press the PRT Key.



Do not move the analyzer until printing is completed.

If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the analyzer. If the results do match, the patient sample should be retested using another cartridge. If they do not match, reprint the results. If the reprint still does not match the analyzer data, the printer requires service and the printed results must not be used.

Storage Conditions and Preparation for Use

Cartridges

- Store at temperatures between 2 and 8 °C (35-46°F). Do not use after expiration date on cartridge pouch and box.
- Equilibrate a single cartridge for 5 minutes or a box of cartridges for 1 hour at room temperature before opening pouches.
- Store cartridges for 2 weeks at room temperature. Mark the cartridge box or cartridge pouches with the room temperature expiration date. Do not expose to temperatures above 30 °C (86°F). Do not return cartridges to the refrigerator after room temperature equilibration.
- Use cartridge immediately after removing from pouch.

Analyzer

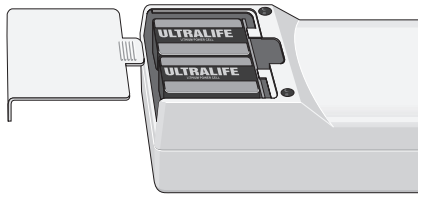
- Storage/Transport temperature: -10 to 50°C (14-122°F)
- The analyzer's operating temperature range is 16 to 30 °C (61-86°F).
- Store analyzers near the testing location or in an area close to the temperature of the testing area. Do not store analyzers near equipment that gives off heat or in direct sunlight.

Hardware Procedures

Replacing the Batteries

- Changing the batteries will not affect stored results or the clock/calendar.

1. Place the analyzer upside down and open the battery compartment door.
2. Remove the old batteries.
3. Orient the (+) and (–) poles of the new batteries with the (+) and (–) labels in the battery compartment and slide the new batteries into place.
4. Close the battery door. The analyzer is ready for use.



NOTE: Only use lithium batteries which are protected against overheating and explosion such as those recommended by i-STAT Corporation.